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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,929	01/22/2002	Julie Straub	ACU 109 CIP	7093

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,929	STRAUB ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/02/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 08/02/05, request for extension of time amendment, remarks and terminal disclaimer, all filed 01/04/05. Claims 16-21 are pending.

Priority

Examiner acknowledges applicants' claim of this application as a continuation-in-part of application serial number 09/433,486 filed 11/04/1999, which claims benefit of Provisional application 60/136,323 filed 05/27/1999 and claims benefit for Provisional application 60/158,659 filed 10/08/1999.

Double Patenting

The submission of a terminal disclaimer overcomes the obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The rejection of claims 16-21 under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. (US 5,976,574) in view of Unger (US 2001/0018072) is withdrawn because Gordon does not disclose a step of combining a volatile solid pore forming agent with drug solution.

3. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger (US 2001/0018072).

Unger discloses solid porous matrix that contains bioactive agent, surfactant and solvent (abstract) and a bicarbonate (paragraph 167); the solvent can be organic or aqueous (paragraph 74); the drying methods include, lyophilizing, spray drying, and the combination thereof

(paragraphs 14 and 76); some of the bioactive agents that can be prepared according to Unger are anti-neoplastic agents, methotrexate, adriamycin (paragraph 135). Surfactant is an excipient. Ammonium carbonate is a volatile pore forming salt. The instant method comprises steps a-d and the steps a-c read on mixing the bioactive agent, the volatile pore forming agent and excipient and removes the solvent by lyophilizing or spray drying. Unger does not specifically disclose the claimed method steps. However, there is no demonstration that the recited method steps provides unexpected results to the porous matrix and also that the specific method steps are known ion the arty for the production of powder formulation (for example, column 2, lines 49-51; column 3, line 30 and column 9, line 41, of US 5,976,574 issued to Gordon, Nov. 02, 1999 a teaching reference discloses preparing powder by dissolving a drug in the solvent, adding excipient to the solution and then spray drying). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a porous matrix according to Unger. One having ordinary skill in the art would have been motivated to use the known steps of preparing the powder with the expectation of forming a porous matrix. In the absence of showing factual evidence, the recited steps of making the porous matrix does not patentably distinguish the claimed invention over the prior art.

Response to Arguments

Applicants argue that Unger does not use a volatile solid pore-forming agent since the blowing agent is methylene chloride, which is a liquid and that Unger does not dissolve the therapeutic agent in the solvent.

4. Applicants' arguments filed 01/04/05 have been fully considered but they are not persuasive.

While Unger discloses incorporating methylene chloride as a blowing agent, Unger discloses the presence of ammonium bicarbonate which upon spray drying would be removed and ammonium bicarbonate is one of the volatile solid pore-forming agents recited in claim 17. The comprising language of the claim is open. Unger discloses using organic solvent as discussed above.

Applicants' argument with regard to Gordon is not persuasive as it refers to the microporous nature of the powder because the claim is directed to a process having steps a-d, but the argument with respect to Gordon not disclosing volatile **solid** pore forming agent is persuasive because Gordon does not disclose volatile solid pore forming agent. Thus the rejection over Gordon in view of Unger is withdrawn.

5. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tarara et al. (US 6,565,885).

Tarara discloses method of preparing perforated microstructure powder formulation (abstract; column 3, lines 42-48, 66, 67; column 4, lines 1-19); the perforated microstructure powder have bulk density of 0.5 g/cm^3 (column 4, lines 20-24); the microstructure powder contains surfactant, excipients bioactive agent, synthetic or natural polymers, rigidifying excipients and ammonium carbonate, ammonium acetate, ammonium chloride and camphor are amongst are few of the salts contemplated for use as rigidifying excipients (column 4, lines 25-46; column 7, lines 8-14; column 11, line 64 to column 12 line 49); the bioactive agents formulated as the powder formulation are listed in column 6, lines 39-52, column line 1 to column 14 line 47; the process involves preparing a feed solution that contains active agent, blowing agent (column 5, line 5 to column 6 line 35) water and volatile solvents (column 22,

lines 32 and 33), ammonium carbonate and camphor, rigidifying excipients (column 16, lines 30-35); processes for drying the feed solution include spray drying, vacuum drying, solvent extraction, emulsification or lyophilization, and combinations thereof (column 5, lines 9, 36; column 15, lines 9-22, 26-67). In another embodiment, the perforated microstructure can be prepared by a double emulsion method where the medicament is first dispersed in a polymer dissolved in organic solvent such as methylene chloride (column 22, lines 40-44). The tap density of the highly porous powder in Tarara is less than 0.1 g/cm^3 (0.1 g/mL) in Examples X-X111.

Although Tarara identifies fluorinated compounds and non-fluorinated oils as blowing agent, the feed solution contains volatile organic compounds such as ammonium carbonate, ammonium acetate, ammonium chloride and camphor are included in the feed solution and lyophilization, vacuum drying or spray drying would remove these compounds and further provide voids in the structure; and also, Tarara specifically discloses the feed solution can also contain compounds that can sublime upon spray drying (column 16, lines 27-33). Ammonium carbonate, ammonium acetate, ammonium chloride and camphor are volatile solids. The polymer and surfactants are excipients. One of the objects of Tarara is stabilized preparation that is suitable for pulmonary administration and the particles of Tarara resist aggregation (column 3, lines 17-33). Although Tarara does not specifically state the amount of active agent present in the powder formulation, it is within the purview of the skilled artisan or the person of ordinary skill to determine the amount of active agent desired in the powder formulation. When the amount of methanol and hot water are excluded since evaporation would remove the volatiles, water removable by vacuum drying or spray drying, the percent amount of the

beclomethasone dipropionate (BDP) in example XI is approximately 13%, which lies within broadly claimed 1-95% of drug in claim 19.

Tarara discloses the process of the claimed invention. Changes in the order of performing the process steps is prima facie obvious in the absence of new and unexpected results and selection of any order of mixing the active agent, solvent, pore forming agent and excipient is prima facie obvious, *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930); *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946). The claimed tap density of the porous powder is less than or equal to 1.0 g/ml. The tap density of the disclosed powder is less than 0.1 g/mL. However, there is no demonstration that the claimed tap density of $\leq$1.0 g/ml provides unusual results. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention to prepare the porous microstructure powder according to the process of Tarara. One having ordinary skill in the art would have been motivated to use the process of Tarara with the expectation of producing porous microstructure and in the absence of factual evidence, the claimed tap density does not distinguish the claimed process over the disclosed process. Both processes lead to porous structures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600